DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

APR 26 2000

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. P.S. Ratra
Managing Director
RFB Latex Limited
Plot 24
Noida Export Processing Zone
Noida, 201305 India

Dear Mr. Ratra:

During an inspection of your firm located in Noida, India on February 28 - March 1, 2000, our investigator determined that your firm manufactures surgical and medical exam gloves. These are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the good manufacturing practice (GMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to base sampling plans on valid statistical rationale, as required by 21 CFR 820.250(b). For example, there has been no statistical rationale to show that a single glove collected at stripping once a month represents the worst case for bioburden analysis.

Your response of March 13, 2000, is not adequate because the letter states that, although a study is being undertaken to demonstrate that one glove collected at stripping once a quarter represents worst case for bioburden, this study is not expected to be completed until Sept. 15, 2000.

2. Failure of the Quality Audit procedures to assure compliance of the Quality System, as required by 21 CFR 820.22. For example, the Internal Quality Audit Procedure, QAP/4.17 references a checklist to be prepared by the auditor but is neither prescribed in the document nor retained afterward to assure complete and consistent audits.

Your response of March 13, 2000, is not adequate. It states that you intend to revise the internal audit procedures to include checklists; however, this revision is not expected to be completed until June 15, 2000.

3. Failure to establish and implement corrective and preventive action procedures to be taken when environmental control limits are exceeded, as required by 21 CFR 820.100(a)(3). For example, the Environmental Control and Housekeeping for bioburden test does not include written procedures for actions to be taken when Alert and Action limits are met or exceeded.

Your response of March 13, 2000, is not adequate. The letter states that you intend to revise the procedures to include actions to be taken when Alert and Action limits are met or exceeded; however, this revision is not expected to be completed until June 15, 2000.

4. Failure of the process control analysis and trending mechanisms to include appropriate product identification for traceability, as required by 21 CFR 820.70(a). For example, trending for in-process, finished product, or complaints does not include the product identification and traceability codes so that trends can be tracked back to specific mixtures, shifts, production lines, or production or sterilization dates.

Your response of March 13, 2000, is not adequate. The letter indicates that you will be revising your tracking procedures; however, this revision is not expected to be completed until June 15, 2000. Further, the investigator was told by you that your firm will soon be converting to a computerized system to track and chart incoming material, in-process, finished product failures and complaints, etc. and intend to take into account the various identification codes.

5. Failure of the Management Representative to follow document control procedures, as required by 21 CFR 820.40(b). For example, the Management Representative revised procedures without following QAP/4.5, Procedure for Document and Data Control, specifically, maintaining a record of changes.

Your response of March 13, 2000, may be adequate because the letter indicates that you now understand the intent of the document control procedures better and intend to follow them.

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). If the causes are determined to be systemic problems, you must promptly initiate permanent corrective actions.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the issuance of government contracts, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that s/he has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the GMP requirements of the Quality System Regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report, and certification by your firm's Chief Executive Officer (CEO) (if other than yourself) that your firm has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

The certification of audits should be submitted to this office by the following date:

- Initial certification by an outside consultant no later than November 1, 2000.

Given the serious nature of these violations of the Act, all devices manufactured by RFB Latex Limited, Plot 24, Noida Export Processing Zone, Noida, 201305 India, may continue to be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review, and have an outside consultant certify your compliance with the Quality System Regulation no later than November 1, 2000. After we notify you that your response is adequate, it will be necessary to schedule an inspection of your facility. Our Division of Emergency and Investigational Operations will contact your facility about scheduling the inspection. As soon as the inspection has taken place and the implementation of your corrections has been verified, your products may resume entry into this country.

Please notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations, for each violation in which the response was less than adequate. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to Ms. Cory Tylka at the above letterhead address. If you have questions or need further assistance contact Ms. Tylka by telephone at (301) 594-4595 or by FAX at (301) 594-4636.

Sincerely yours,

Reva L. Melton

for Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure: Selecting a Consultant?

Purged
CRT
4/28/00